Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12950

0 - FRONT

COMPLAINT/INJURY REPORT #12950

1. COMPLAINT NUMBER: LOS-8148

2. DATE OF COMPLAINT (MM/DD/YY): 06/10/98

3. FORM OF COMPLAINT: ☒(1) TELEPHONE ☐(3) VISIT ☐(2) LETTER

4. SOURCE OF COMPLAINT: ☒(1) CONSUMER ☐(2) GOVERNMENT ☐L ☐S ☐F ☐(3) TRADE SOURCE ☐(4) OTHER *(Indicate in Remarks)*

5. COMPLAINT IDENTIFICATION

a. NAME AND ADDRESS *(Include Zip Code)*
[redacted]

b. AREA CODE AND TELEPHONE
HOME [redacted]
WORK( )

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT/INJURY

The complainant is a 28 year-old black female who was in good health prior to the adverse event. She has no known allergies, preexisting medical conditions nor treatment. On May 15 1998, she purchased one bottle of Chinese Phen-Chi for weight loss from [redacted]. This was the first time she purchased and used the product. The complainant also mentioned that she was taking multivitamins along with Chinese Phen-Chi. On May 16th, the complainant started taking two tablets before breakfast and two tablets before lunch. Continue in Remarks section.

DOES COMPLAINT EXPECT ADDITIONAL FDA CONTACT? ☒ NO ☐YES *(Explain in Remarks)*

7. INJURY OR ILLNESS RESULTED ☐(1) NO ☒ (2) YES (If "YES" complete items a through d)

a. EIB (HFC-134) NOTIFIED ☐(1) NO ☒ (2) YES DATE: 06/11/98 FAXED

b. TYPE SYMPTOMS — ONSET (HR.)
☐(1) VOMITING —
☐(2) NAUSEA —
☐(3) DIARRHEA —
☐(4) FEVER —
☐(5) SKIN/EYE IRR. —
☐(6) HEADACHE —
☒ (7) OTHER-CHEST PAIN & SOB —

c. ATTENDING HEALTH PROFESSIONAL ☐(1) NO ☒ (2) YES (If "yes" give name address, and phone no.)
[redacted]

d. HOSPITALIZATION REQUIRED ☒ (1) NO ☐(2) YES (If "yes" give name address, and phone no. and dates)

8. PRODUCT AND LABELING

a. BRAND NAME: NATURE'S SUNSHINE

b. PRODUCT NAME: CHINESE PHEN-CHI

c. SIZE AND PACKAGE TYPE: DID NOT RECALL

d. NAME AND LOCATION OF STORE WHERE PURCHASED
[redacted]

e. PACKAGE CODE/SERIAL NUMBER/ETC.: STOCK # 2925-3 EXP/USE BY DATE:

f. DATE PURCHASED: 5/15/98

g. PRODUCT USED (If "yes" enter date): 5/16/98 ☐(1) NO ☒ (2) YES

h. AMT REMAINING: NONE

RECEIVED JUN 15 1998

9. MANUFACTURER/ DISTRIBUTOR OF PRODUCT

a. HOME DISTRICT: DEN-DO (8)

b. C.F.NO.: 1719247

c. NAME AND ADDRESS OF FIRM (Include Zip Code)
NATURE'S SUNSHINE
SPANISH FORK, UT 84660

d. IMPORT PRODUCT ☒ (1) NO ☐(2) YES

10. EVALUATION AND DISPOSITION

a. PROBLEM KEYWORD
(1) CODE (2) DESCRIPTION
RX CHEST PAINS

b. EVALUATION
☐(1) NOT AN FDA OBLIGATION
☐(2) OBLIGATION, NO VIOLATION
☒ (3) FDA ACTION INDICATED
☐(4) INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
☐(1) IMMEDIATE FOLLOW-UP
☐(2) F/U NEXT EI
☐(3) CLOSED WITHOUT FURTHER INVESTIGATION
☐(4) REFERRED TO OTHER FEDERAL AGENCY *(Closes file)*
☐(5) REFERRED TO STATE/ LOCAL AGENCY
☒ (6) REFERRED TO OTHER FDA 8 DISTRICT

11. PRODUCT CODE: 54FEA09

12. INFORMATION COPIES TO:
☐HFM - 660 *(Biologics)* ☐HFZ - 530
☐HFD - 730 ☐HFS - 106
☒ HFS - 635 ☒ HFC - 134
☐HFV - 210 ☐__

REMARKS

Block #6a. On May 21th, she experienced chest pains and shortness of breath. She sought medical attention at [redacted] Room (ER). She was in the ER waiting room from 12:30 a.m. to 4:00 a.m. and left without medical treatment. On May 22nd, she sought treatment at [redacted]. Dr. [redacted], a ER physician examined the complainant and ordered a EKG and chest X-rays. She did not know the results of the tests. She was given a shot of Activan and released the same day of ER visit. The Releasing Diagnosis were inflammation of the chest muscles. She was instructed to stop taking the product and was given a prescription of Activan one tab every night as needed. The complainant returned product to the store of purchased and received a refund. The complainant is still experiencing sharp chest pains. She has not returned to the doctor for follow-up.

ATTACHED: Adverse Event Questionnaire, dated 6/11/98.

NAME AND TITLE: HENRY E. CARRILLO, CSI

DATE: 6/11/98

FORM FDA 2516 (4/85) WHITE PINK BLUE YELLOW GOLD

000001

Adverse Event Questionnaire

Complaint Number: LOS-8148

Investigator: HENRY E. CARRILLO, CSI

Consumer Information

Date of Report: 06/11/98
MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury
☒Telephone ☐Correspondence ☐MedWatch
☐USP ☐PQRS ☐Poison Control ☐CDC

Name: [redacted]

Gender: ☒F ☐M

Age: 28 YRS.

Race: ☐1-White ☒2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic
☐8-Other ☐9-Unknown

Information on Adverse Event

Date of Adverse Event:05/21/98
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office):*Home.*

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms):
Five days after taking product, she experienced sharp chest pains and shortness of breath.

How long did the symptoms last? ***To date, the complainant still complains of chest pains.***
Give the circumstances of exposure (i.e. how much was taken, how was the product taken and how often was it taken, etc.).
Took two tablets one hour before breakfast and two tablets again before lunch, a total of four tablets a day for five days.

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event:
Multi-vitamins.

Did event abate after use of suspected product stopped or dose reduced: ☐Yes ☒No ☐Unknown
Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ☐Unknown ☒XNot Applicable
Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

Was a health care provider seen?: ☒Yes ☐No
Give health care provider's name, address and telephone number: ***Dr.*** [redacted] ***attending emergency room physician at*** [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist
☐Other (specify)

What medical tests were performed and what were the results?
EKG and chest X-rays. The results are unknown.
What was the medical diagnosis? ***Inflammation of the chest muscles.***
What treatment(s) was given (e.g., drugs, other)?
A shot of Activan during ER visit, and prescription of Activan, one tablet every night as needed.

Were there any preexisting condition(s)/treatment(s)? ***None***
(If YES, list them including allergies, and chronic diseases): ☐Yes ☐No

Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐Other (traditional food) _____

Other Product Problems

2. ☐Foreign Object (specify): _____

3. ☐Other (specify): _____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):
Brand: Nature's Sunshine, Product Name: Chinese Phen-Chi
Nature's Sunshine, Spanish Fork, UT 84660.
For weight loss. The complainant returned product to the store of purchase and received refund. The product instructions are unavailable at this time.

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☒Check here if ingredients are unknown

_____

_____

_____

_____

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame ☐Color Additive (please specify) _____
☐Monosodium Glutamate
☐Sulfite
☒Other *Ephedrine containing product*
☐Unknown

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐Yes ☒No ☐Unknown Product Sample Available: ☐Yes ☒No ☐Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐Yes ☒No

Life-Threatening: ☐Yes ☒No

Hospitalization: ☐Yes ☒No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐Yes ☒No

Did the adverse event result in a congenital anomaly: ☐Yes ☒No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

June 12, 1998

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Division of Field Program Planning and Evaluation (HFS-635)
Attn: Adverse Reaction Monitor
200 C Street SW
Washington DC 20240

Re: Consumer Complaint Number: LOS-8148

Dear Adverse Reaction Monitor:

Enclosed is a copy of a consumer complaint received by our district. We are forwarding a copy of the complaint and a Adverse Event Questionnaire to you according to Field Management Directive, No. 119, and the Investigations Operations Manual, Chapter 9.

If you have any questions, call me at (949) 798-7701.

Sincerely,

Henry E. Carrillo
Consumer Complaint Coordinator
Los Angeles District